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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,991	07/26/2001	John Paul McGee	JANS-0008	7988

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EXAMINER

FUBARA, BLESSING M

ART UNIT PAPER NUMBER

1615

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/868,991

Applicant(s)

MCGEE ET AL.

Examiner

Blessing M. Fubara

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-15 and 17-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-7, 10-12, 14, 15 and 17-29 is/are rejected.
- 7) ☒ Claim(s) 8, 9 and 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>04/26/04 & 8/06/04</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1615

DETAILED ACTION

Examiner acknowledges receipt of IDS filed 04/26/04 and 08/06/04, amendment and remarks filed 05/19/04.

Claim Rejections - 35 USC § 101

Claims 23-25 remain rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Applicants state, "claims 23-25 are directed to a pharmaceutical package with variously explicitly recited material components." Thus applicants conclude "these claims are directed to articles of manufacture which are statutory under 35 USC 101."

1. Applicants' arguments filed 05/19/04 have been fully considered but they are not persuasive.

Claim 23, line 3 recites and claims "written matter specifying how said formulation should be administered," and this recitation claiming a mere arrangement of words on a piece of paper, in this case a package, is a claim to printed matter; and printed matter is non statutory. See *In re Miller*, *Ex parte Gwinn* and *In re Jones*.

Claim Rejections - 35 USC § 112

2. The rejection of claims 2-15 and 17-29 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of the amendment.

Art Unit: 1615

3. Claims 5-7, 14, 15, 17-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5, line 2, recites, "comprising" for a Markush claim and thus the claim is of an improper Markush format. The claim may read ---consisting of--- in place of the comprising to comply with the Markush type claim.

Claim Objections

4. Claim 19 remain objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Claim 19 refers to two sets of claims, in one set, the claim depends on a multiple dependent claim and in line 3, the same claim depends on claim 10. Correction is respectfully requested.

5. The objection of claims 15, 17, 18 and 21 under 37 CFR 1.75(c) as being in improper form is withdrawn in light of the amendment.

6. Claim 22 remain objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Claim 22 does not refer to the multiple claims in the alternative.

Claim Rejections - 35 USC § 102

7. Claims 2-6, 10, 11, 17, 22, 23 and 25 remain rejected under 35 U.S.C. 102(b) as being anticipated by Davis et al. (CA 1326632).

Art Unit: 1615

Applicants argue that Davis does not disclose water insoluble polymer and that polyvinylpyrrolidone is disclosed in the instant specification to be water-soluble.

8. Applicants' arguments filed 05/19/04 have been fully considered but they are not persuasive.

It is noted that generic claim 10 is directed to water-soluble polymer and also to water insoluble polymer. Davis discloses polyvinylpyrrolidone, which is water soluble as pointed to by applicants in the remarks. Davis also discloses the presence of a coating material of ethyl cellulose, which is water insoluble. Mixing particles with excipients or coating polymer is one of the ways of carrying out a coating process. Plasticizer is optional in claim 10 and thus not necessarily have to be present in the formulation. Thus Davis discloses all the necessary elements of the rejected claims.

Claim Rejections - 35 USC § 103

9. Claims 7, 12, 14, 15, 18-21, 24 and 26-29 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. (US 4,663,318).

Applicants argue that Davis does not disclose a water insoluble polymer and as such there cannot be a prima facie case of obviousness.

10. Applicants' arguments filed 05/19/04 have been fully considered but they are not persuasive.

As discussed above, Davis discloses water insoluble polymer and therefore, the rejection is proper.

Although the art rejections on record are maintained, the rejection is non-final because claim 5 is newly rejected as of improper Markush type claim.

Art Unit: 1615

11. Claims 8, 9 and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

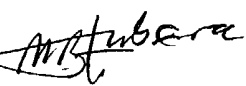
Observation:

Dependent claims depend on preceding claims. However, claims 2-9 depend directly or indirectly on claim 10.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara 
Patent Examiner
Tech. Center 1600